Quarterly Progress Report #3

N01-NS-5-2365

Restoration of Hand and Arm Function by Functional Neuromuscular Stimulation

Period covered: April 1, 2006 to June 30, 2006

Principal Investigator: Robert F. Kirsch, Ph.D.

Program Manager: William D. Memberg, M.S.

Case Western Reserve University
Wickenden 115
10900 Euclid Avenue
Cleveland, OH 44106-7207
216-368-3158 (voice)
216-368-4969 (FAX)
rfk3@case.edu

A. Executive Summary

1. Contract goals

The overall goal of this contract is to develop and deploy a family of neuroprostheses that can restore arm and hand function to almost any individual with significant paralysis due to cervical spinal cord injury. This contract includes three primary components that are aimed at making this possible:

a. <u>Technology development</u>

i. Development of an implantable 4-channel EMG module by an industrial partner
ii. Purchase of an implantable 8-channel stimulation module from an industrial partner
iii. Development of a fully implanted bipolar EMG electrode

b. <u>Neuroprosthesis deployment</u>

i. 8-channel stimulation, switch-controlled neuroprosthesis for C6 SCI (4 participants)
ii. 16-channel stimulation, 8-channel EMG controlled neuroprosthesis for C5-C6 SCI (4 participants)
iii. 16-channel stimulation, 8-channel EMG controlled neuroprosthesis for C1-C4 SCI (1 participant)

c. <u>Development of high performance command and control interfaces</u>

i. EMG-based control approaches
ii. Integration of brain-machine interfaces into neuroprosthesis control

2. Overview of this reporting period

During this three-month period, we produced a second prototype for the intramuscular MES electrode, translated the Dynamic Arm Simulator software into the Simulink environment (thus enabling greatly improved real-time performance), developed a simplified virtual reality training environment for evaluating user command interfaces for hand movement and orientation control, and negotiated details regarding the size, battery capacity, and connector types to be used on the MicroPulse stimulator and EMG modules.

B. Activity Summary

- A second prototype of the intramuscular MES electrode tip was fabricated. Regulatory issues for the electrode were investigated.
- Matlab code for the Dynamic Arm Simulator was converted to Simulink. Variable moment arms were implemented in the 2 DOF model. The hybrid controller development continued.
- A virtual reality 'Pacman'-hand training environment was developed for display to subjects of X, Y, & Z hand position in space, hand opening and closing, and multiple wrist rotations.

- Final design parameters of the MicroPulse system (both the stimulator module and the EMG module) were discussed with NDI Medical and other investigators in the FES Center.

C. Research Results and Discussion

1. Development of a Fully Implanted Intramuscular Bipolar MES Electrode

Activity Summary:

- A second prototype of the intramuscular MES electrode tip was fabricated.
- Regulatory issues were investigated.

Rationale:

We currently use epimysial-based MES electrodes in our stimulation systems. While these work well, the epimysial recording electrodes may be difficult to implant if the target muscle is small or deep. Epimysial electrodes also require surgical incisions to expose the target muscles, and their implantation can be time-consuming if many electrodes are being implanted

The intramuscular stimulating electrode (IM-STIM) that is in current use is able to access small and/or deeper muscles of the hand and forearm while minimizing incision size and implantation time. The IM-STIM electrode has been shown to have excellent tissue response characteristics and long-term durability. It is anticipated that modifying the IM-STIM design to create an intramuscular bipolar MES electrode (IM-MES) would provide similar benefits.

Results:

Recording Tip Prototypes

In the last quarterly progress report, an initial prototype of the IM-MES electrode tip was described. In this prototype, the two conductors were deinsulated where they exit the tubing. One of the conductors was then wrapped around the outside of the tubing for 4 mm and was then inserted back into the tubing. The second conductor was fed back inside the tubing to a small hole in the tubing 10 mm from the end. It then exited the tubing, was wrapped around the tubing for 4 mm and inserted back into the tubing.

Due to concerns about the potential stresses on the 10 mm straight section of the second conductor that was fed back inside the tubing, a variation of the tip design was fabricated. In this design, one conductor is deinsulated where it exits the tubing and is wrapped around the outside of the tubing. A second section of tubing is placed over the second conductor, which is still insulated and helically coiled. At the end of the second section of tubing the second conductor is deinsulated and is wrapped around the outside of the tubing. The two sections of silicon tubing are held together with silicon adhesive.

Regulatory Issues

A review was made of the FDA investigational device exemption (IDE) for the currently-used implantable stimulation devices at our center. The section on MES recording electrodes covers both epimysial and intramuscular recording electrodes. The explanation of the intramuscular recording electrode is an accurate description of the current design plans, so it appears that we do not need to submit an IDE amendment to the FDA. The FDA will be notified that we will be using the intramuscular MES electrode prior to human implantation.

The research protocols approved by our local IRBs do not include intramuscular MES electrodes, so amendments to these protocols will be submitted and all new protocols associated with this project will include the use of these devices.

Discussion and interpretation:

Both prototypes of the stimulating tip satisfied the design specifications for the IM-MES electrode and are not difficult to fabricate.

It appears that regulatory approval of the IM-MES should be relatively straightforward

Future plans:

The two design prototypes for the recording tip will be analyzed by a design review team. In addition, the mechanical characteristics of the wire that will be used in these electrodes are currently being evaluated as part of a different project. This characterization includes fatigue testing of straight sections of wire, which will be directly applicable to the first prototype design.

Also in the next quarter, commercially available pealable sheaths will be investigated to see whether they would be useful for the IM-MES insertion.

2. Development of a Real-Time Model of the Human Arm and Hand

Activity Summary

- Conversion of Matlab code to Simulink.
- Implementation of variable moment arms in 2 DOF model.
- Hybrid controller development.

Rationale

It was decided to implement the 2 DOF model in Matlab's Simulink framework, which allows easy integration with their Real-Time Workshop. This has some significant advantages over Matlab's m-file format:

- rapid code development, particularly controller design;
- tight integration with Matlab VR toolbox (Simulink is Matlab's recommended method for use of the VR toolbox) and other data passing over ethernet connections;
- easy deployment to x86-based real-time system via xPC Target.

Some modest re-writing of the code is necessary to implement the model in Simulink, but this investment will allow much easier development of the model in future versions, as well as easier integration with other components of the simulator.

Work has been carried out during this period to define the muscle moment arms of the 2 DOF model more realistically, including the change of the moment arms as they wrap around the bony surfaces of the joints. This change should lead to the muscles acting over a more physiologically realistic range of the force-length curve and improve the controllability of the model. Previously the simplification of constant moment arms led to unrealistically large muscle excursions, resulting in difficulty controlling the model. This has also allowed refinement of the techniques that will be needed to accurately model the moment arms in future, more complex versions of the model.

Results

Figure 1 shows the change in joint angles following a single end-point position command as input, using the hybrid controller. The vertical axis shows the error between the desired joint angles and the actual angles. The error should of course drop to zero when the system reaches a steady state. In the task shown, the model was given a step input (from (0, 0) to (20, 120) degrees of shoulder and elbow flexion respectively). The model was able to reach the target position in approximately 6 seconds (120 samples), displaying minimal overshoot and a small steady-state error. These results use the constant moment arm model, in which the gains must be kept fairly low in order to ensure stability of the model. Tests of the variable moment arm model, which should allow higher gains to be used without compromising stability, are underway and will be reported in an upcoming progress report. Higher gains will allow the model to reach the steady-state condition in a shorter time.

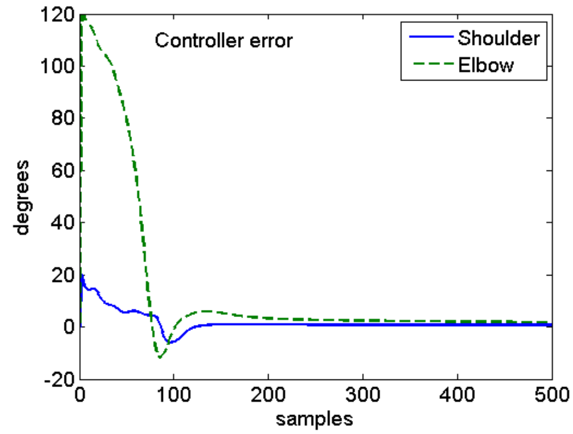

Figure 1. Joint angles controlled by a hybrid controller, with a low steady-state error.

Discussion and Interpretation

Analysis of the function of the hybrid controller outlined in the previous quarterly progress report showed that certain simplifications of the model had a negative impact on its controllability. Namely, the use of constant muscle moment arms in the 2 DOF model led to the excursion of the muscles being too high during the normal range of motion movements and the muscles operating outside of their normal force-length curve. This had a negative impact on the stability of the model in certain positions. The addition of variable moment arms to the next version should improve controllability of the model.

Future Plans

Work for the next two reporting periods will focus on:

- finalizing the conversion of the 2 DOF (DAS1) model to Simulink;
- refining the feedback controller for DAS1;
- building the 5 DOF version of the simulator (DAS2).

Development of Simplified Virtual Training Tool for Distribution to the Research Community in Conjunction with the Dynamic Upper Extremity Simulator.

Activity Summary: - Developed a simplified virtual reality ‘pacman hand’ training environment for display of X, Y, & Z hand position in space, hand opening and closing, and multiple wrist rotations. This version of the virtual ‘hand’ and target system is specifically designed to *not* require expensive 3D stereo monitors or high-resolution graphics systems to adequately represent 3D hand position and orientation. It is also designed to enable more accurate evaluation of the command signal precision.

Rationale: As part of this contract, we will be making the dynamic upper-extremity simulation tool and a realistic virtual hand/arm training interface available to the research community in order to encourage the development and comparison of cortical recording and decoding methods most appropriate for command of an upper-limb neuroprosthesis. However, not all researchers will have the extra computational power, high-end graphics cards, and 3D stereo monitor needed to adequately view the realistic virtual human hand in real time. In addition, evaluation of the user's ability to *precisely* match specific brain-controlled hand positions/configurations to 'target hand' positions/configurations is difficult with a realistic virtual limb because of viewing complications (e.g. obscuring of actual hand by target hand or visa versa; perception complications if making complex hand objects transparent to prevent obscuring, etc.). This simplified abstract hand now enables testing of precise matching of the brain-controlled hand position/configuration to target hand position/configurations without confounding the results with the inherent limitations of viewing the more realistic limb.

Finally, this more abstract hand image can be used by researchers working with either human or monkey models. By providing an effective visual feedback approach that can be used by a wide variety of research groups, more people in the research community can become involved with the development of command source interfaces specifically for the upper limb neuroprosthesis.

Results: We have developed a pacman-like virtual hand and target representation that can be driven by decoded cortical or other command signals after those commands are processed by

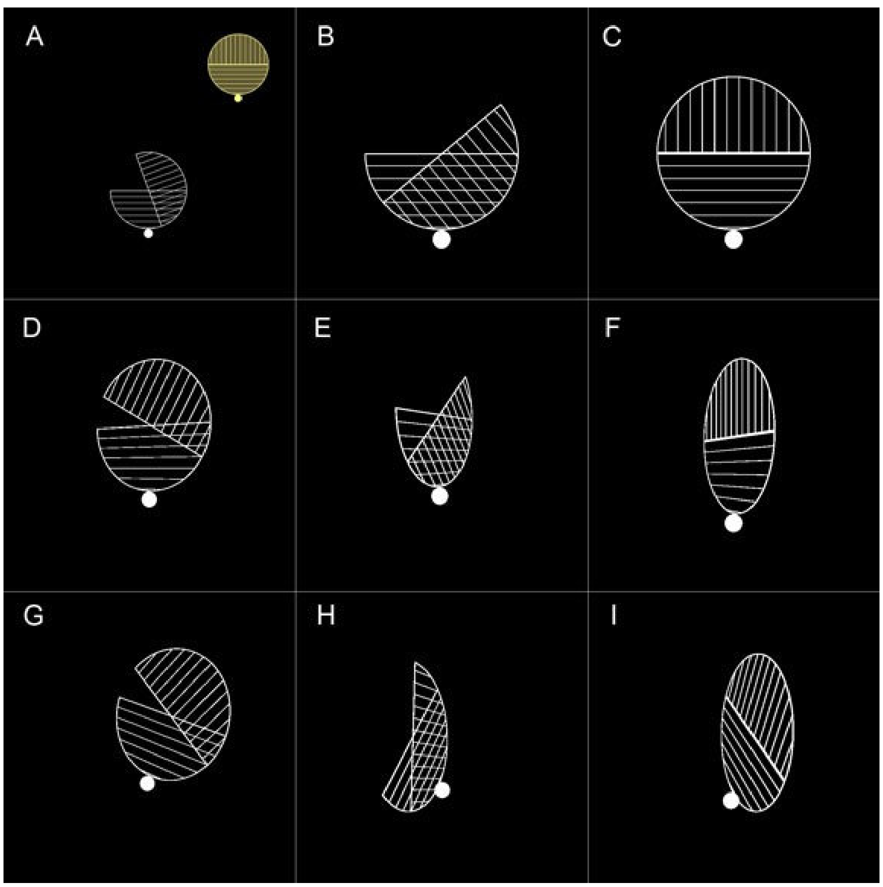

Figure X: Virtual Interface for Intracortical Command Source Evaluation: A) subject-controlled hand (center) and more distant target hand (upper right corner). Note the depth component of the 3D position can be conveyed even without a stereo monitor because the hand gets smaller as it moves away from the subject and larger as it moves closer to the subject. Parts B through I show enlarged examples of possible hand configurations. B&C) just show hand opening and closing, D-F) include one additional wrist rotation, G-I) include two wrist rotations.

the dynamic upper-extremity simulator to give a realistic representation of what the resulting FES arm/hand movements would be. Previous simplified virtual reality interfaces used by our lab and others have used 3D shaded spheres displayed on stereo monitors to represent 'hand position' in 3D space or spheres and cylinders to represent position and orientation. In those cases, making the virtual objects transparent was necessary to enable the subjects to see both the target and 'hand' at the same time. Key features of our new pacman hand interface are:

- the use of bars instead of translucent solids to enable easy viewing of both the 'target hand' and 'subject-controlled hand' even when one is in front of the other. This eliminates the need for a high-end graphics card to adequately render translucent objects in real time.
- inclusion of a means to display degree of hand open/close
- By generating 'target hands' and 'subject-controlled hand' that are of identical size mathematically, the relative difference in their size on the screen can be used to convey the relative difference in the depth component of their 3D position using a standard non-stereo screen (i.e. closer hands/targets will be displayed as larger than more distant hands/targets). To further facilitate this size-based depth perception, flat disk-like hand representations are used instead of spherical representation because the soft, graded edge shadows seen on spherical representations 'fuzzied' the perception of relative size making it more difficult to perceive the depth component without a 3D stereo monitor.

We have tested the ability to perceive the 3D position, orientation, and degree of hand opening and closing using three naïve human subjects in a hand/target-matching task. Subjects controlled their hand representation based on actual hand movements tracked via an optotrak motion capture system in real time. Subjects easily learned to match both position and configuration of the subject-controlled hand to the target hand.

<u>Discussion and interpretation</u>: By making a visually simplified version of this training tool, we are now able to more precisely test control of the different degrees of freedom of a brain-controlled virtual hand without the confounding factors of the perception difficulties that occur when using the realistic virtual hand. By developing an effective interface that can be used without high-end graphics processing and expensive 3D stereo monitors, we will enable researchers working with both human and monkey subjects to use these tools with their current equipment. This will facilitate our efforts to compile a database comparing the effectiveness of the different recording technologies and decoding methods used by researchers around the world for precision arm/hand control.

<u>Future plans</u>: We are in the process of incorporating this virtual interface with a more flexible set of software tools that will be able to utilize discrete commands in addition to multiple proportional commands. These discrete commands can be used to:

- enable 'mode switching' to toggle control between different subsets of movement degrees of freedom (e.g. use 3 proportional signals to first control XYZ position, and then use a discrete command to switch the control to hand opening/closing, pro/supination, and wrist flexion/extension).
- Trigger preprogrammed movements (e.g. move hand from current position to mouth).

This improved form of the training and evaluation tool will enable research groups that can only produce a limited number of proportional and/or discrete commands to test their abilities to use their command signals to generate a full complement of useful movements using the pacman and/or human hand virtual interfaces.

Design Specifications for MicroPulse II and MicroPulse EMG modules

Activity Summary: Contract personnel (Kirsch, Kilgore, Peckham, and Memberg) have participated in detailed discussions with NDI Medical to finalize several key parameters of the MicroPulse family of modules, including final size, battery capacity, and connector type and locations on the modules.

Rationale: All of the implanted neuroprostheses to be deployed under this contract will use commercially manufactured stimulator and EMG modules developed by a collaboration between NDI Medical and investigators in the Cleveland FES Center, including the investigators on this project. Ongoing discussions have been held to finalize design parameters so that the resulting modules can meet all needed stimulation and recording requirements, have a battery capacity adequate for a full day of operation, and can be contained within a package small enough to be implanted unobtrusively in the upper chest and abdomen.

Results and Discussion: A number of different configurations have been considered, with different numbers of channels, different types of connectors for plugging leads into the modules, different locations for the connectors on the implant modules, and different battery sizes. After a series of meetings, the chosen configuration will have 8 channels per module, a package size of 55 mm by 39 mm (determined largely by the battery capacity), and cardiac pacemaker-standard IS-1 connectors oriented along the long axis of the module (two per end, each with two channels for a total of 8 channels). This design minimizes package size, results in connector locations that will be easier for surgeons to access, uses industry-standard connectors that can be used off-the-shelf, and allows a battery capacity sufficient for a full day of use between charges.

Interpretation: The revised MicroPulse design is slightly different than originally proposed, with a slightly larger enclosure to allow longer battery life. Otherwise, the originally proposed design of 8 stimulation channels (or 4 bipolar EMG channels) and industry-standard cardiac pacemaker connectors is preserved.

Future plans: Work will now proceed to finalizing the circuit designs for the stimulation channels (for the stimulating module) and the recording channels (for the EMG module). The development schedule for both the stimulator module and the EMG recording module are still on target to meet the planned schedule for deploying the proposed implanted neuroprosthesis systems.

D. Concerns

There are no significant concerns at this time.